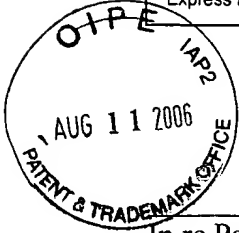


IFW 1616 ~~18~~

Express Mail Label No. \_\_\_\_\_ Dated: \_\_\_\_\_

Docket No.: 04368/000J367-US0  
(PATENT)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Patent Application of:  
Azariah Jossifoff**

Application No.: 09/856,417

Confirmation No.: 7902

Filed: August 8, 2001

Art Unit: 1616

For: VAGINALLY ADMINISTRATABLE  
PROGESTERONE-CONTAINING TABLETS  
AND METHOD FOR PREPARING SAME

Examiner: A. N. Pryor

## **SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

(Check one of the boxes A-D)

- ☐ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☐ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☒ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was  
(check one of boxes (a) or (b))
- ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- ☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☒ ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(i) a check in the amount of \$180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was  
(check one of boxes (a) or (b))
- ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- ☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

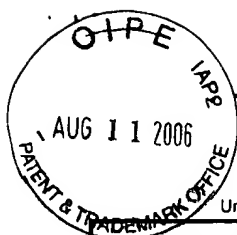
2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☐ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) \_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.







PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031  
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Substitute for form 1449A/B/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			Application Number	09/856,417-Conf. #7902	
			Filing Date	August 8, 2001	
			First Named Inventor	Azariah Jossifoff	
			Art Unit	1616	
			Examiner Name	A. N. Pryor	
Sheet	1	of	1	Attorney Docket Number	04368/000J367-USO

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	CA	Bulletti, C. et al., Targeted drug delivery in gynaecology: the first uterine pass effect, Human Reproduction, 1997, vol. 12, pp. 1073-1079		
	CB	Ficicioglu, C. et al., High local endometrial effect of vaginal progesterone gel, Gynecol Endocrinol., 2004, vol. 18, pp. 240-243		
	CC	Levy, T. et al., Pharmacokinetics of natural progesterone administered in the form of a vaginal tablet, Human Reproduction, 1999, vol. 14, pp. 606-610		
	CD	Levy, T. et al., Pharmacokinetics of the progesterone-containing vaginal tablet and its use in assisted reproduction, Steroids, 2000, vol. 65, pp. 645-649		
	CE	Lewin, A. et al., Simplified artificial endometrial preparation, using oral estradiol and novel vaginal progesterone tablets: a prospective randomized study, Gynecol Endocrinol, 2002, vol. 15, pp. 131-136		
	CF	Maymon, R. and Schulman, A., Comparison of triple serum screening and pregnancy outcome in oocyte donation versus IVF pregnancies, Human Reproduction, 2001, vol. 16, pp. 691-695		
	CG	Schulman, A. et al., The best donor, Human Reproduction, 1999, vol. 14, pp. 2493-2496		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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Application No. (if known): 09/856,417

Attorney Docket No.: 04368/000J367-US0

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